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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,068	03/05/2002	H. Garrett Wada	100/08711	7955

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,068	WADA ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/03, 3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 20 January 2004 in which claims 1 and 20 were amended and claims 2-3 and 21-28 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated17 November 2003 are withdrawn in view of the amendments and Applicant's remarks on page 5 of the response regarding "non-protein molecule". New grounds for rejection are discussed.

The examiner for this application has changed. Please address future correspondence to BJ Forman, Art Unit: 1634.

Claims 1 and 4-20 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent

> or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The claims are drawn to a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a labeled second component of the binding reaction.

The claims are interpreted as a system requiring the presence of the cell suspension within at least the first channel, and further requiring the presence of first and second components of a binding reaction. The claims are further interpreted as encompassing the second component of the binding reaction as being within the reaction vessel, within the channel or within the cell suspension or within the cells.

The specification broadly defines the claimed "intersecting microfluidic channels" at page 17, lines 11-16 as follows:

> Accordingly, the microfluidic devices or systems prepared in accordance with the present invention typically include at least one microscale channel, usually at least two intersecting microscale channels, and often, three or more intersecting channels disposed within a single body structure. Channel intersections may exist in a number of formats, including cross intersections, "T" intersections, or <u>any number of other structures whereby two channels are in fluid communication.</u>

Hence, the claimed intersecting microfluidic channels encompass any number of other structures whereby two microfluidic channels are in fluid communication.

4. Claims 1, 4 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al (U.S. Patent No. 5,486,335, issued 23 January 1996).

Regarding Claim 1, Wilding et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component (i.e. immobilized antibody) having a fluorescent labeled lectin "associated therewith" (Column 6, lines 25-46; Column 8, liens 10-29; Example 3: Column 11, lines 40-55 and Fig. 9-13).

Regarding Claim 4, Wilding et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component i.e. immobilized antibody (Example 3: Column 11, lines 40-55).

Regarding Claim 19, Wilding et al disclose the system wherein the cells are mammalian (Example 3: Column 11, lines 40-55).

5. Claims 1, 4 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Parce et al (U.S. Patent No. 5,942,443, issued 24 August 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, Parce et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component (i.e. test compound) having a fluorescent labeled "associated therewith" (Column 7, line 40-Column 8, line 57 and Claim 7)

Regarding Claim 4, Parce et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component (Column 4, line 58-67 and Column 6, line 60-Column 7, line 2).

6. Claims 1, 4 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al (U.S. Patent No. 6,074,827, filed 5 February 1998).

Regarding Claim 1, Nelson et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component having a fluorescent labeled "associated therewith" (Column 10, lines 35-47; Column 20, line 58-Column 22, line 52; Column 23, line 46-Column 24; and Fig. 27).

Regarding Claim 4, Nelson et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component i.e. immobilized antibody (Column 21, lines 25-49).

Regarding Claim 19, Nelson et al disclose the system wherein the cells are mammalian (Column 26, line 45-Column 27, line 9).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 5-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (U.S. Patent No. 6,074,827, filed 5 February 1998).

Regarding Claim 5-18 and 20, Nelson et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component having a fluorescent labeled "associated therewith" (Column 10, lines 35-47; Column 20, line 58-Column 22, line 52; Column 23, line 46-Column 24; and Fig. 27).

Furthermore, Nelson et al teach their system comprises detection of various cells and/or cell components within the microfluidic channel e.g. nucleic acids, oligonucleotides, proteins, peptides, lipids and etc. (Column 26, line 45-Column 27, line 9) but they do not specifically teach the first and second binding partners recited in Claims 5-18 and 20.

However, the cellular components taught by Nelson are genus of the instantly claimed species which clearly suggests the claimed species.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the genus teaching of Nelson et al and to provide their system with the instantly claimed species based on the suggestion to do so of Nelson et al (Abstract).

9. Claims 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al (U.S. Patent No. 5,942,443, issued 24 August 1999).

Regarding Claims 5-20, Parce et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component (i.e. test compound) having a fluorescent labeled "associated therewith" (Column 7, line 40-Column 8, line 57 and Claim 7).

Parce et al further teach the test compound comprises peptides, proteins, nucleic acids, small organic and small inorganic molecules (Column 4, line 58-67 and Column 6, line 60-Column 7, line 2) whereby biological interactions are analysis e.g. cellular signaling, transport reactions involving cells, cellular viability and in vivo effectors (Column 4, lines 40-67). This teaching clearly suggests the instantly claimed binding partners of less than 50 amino acids (peptides), carbohydrates, lipids, cAMP (effectors), nuclei acid binding protein-nucleic acid probe (nucleic acids), translocation functionality (transport reactions) and signaling pathway (cellular signaling) but they do not specifically teach the first and second binding partners

recited in Claims 5-18 and 20. However, the cellular components taught by Parce are genus of the instantly claimed species which clearly suggests the claimed species.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the genus teaching of Parce et al and to provide their system with the instantly claimed species based on the suggestion to do so of Parce et al (Abstract).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 1, 2004